IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Ameae M. Walker

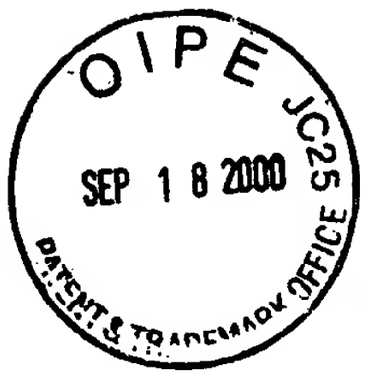
Serial No.: 09/065,330

Filed: April 23, 1998

For: PROLACTIN ANTAGONISTS AND USES THEREOF

Group Art Unit: 1646

Examiner:
Christine Saoud, Ph.D.



San Francisco, California

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on September 13, 2000.

Sarah Lyn Torres

Sarah Lyn Torres
Signature

9/13/00
Date

DECLARATION OF AMEAE M. WALKER

I, Ameae M. Walker, declare as follows:

1. I am a Professor of Biomedical Sciences at the University of California, Riverside, California. I received my Ph.D. in 1976 in the field of cell biology.

2. In its early stages, prostate cancer growth is promoted by male sex hormones (androgens). Therapy with anti-androgens, drugs which block the effects of male sex hormones, effectively control growth. Eventually, all prostate cancers lose their responsiveness to anti-androgens. There is currently no good therapy available for later stages of prostate cancer. The

prostate grows in response to the hormone, prolactin. Cells derived from patients with late stage prostate cancer still grow in response to prolactin. Late stage prostate cancer cells make their own prolactin which they use to promote their own growth. Tumors in late stage prostate cancer grow in a self-perpetuating growth loop.

3. I performed two trials in which I assessed the effect of a human prolactin mutated at serine 179, as described in the subject application where serine is substituted by an aspartate residue, on the growth of late stage human cancer in an animal model.

4. In the first trial, three groups of 11 animals each were given a constant dose of this mutated human prolactin, beginning four days prior to injection of 5 million human cancer cells. Only 27% of these animals developed tumors compared with 82% of those not given the mutated prolactin.

5. In the second trial, tumors were grown for 18 days and then a constant dose of this mutated human prolactin was administered for 24 days. At the end of this 24-day period, the tumors were half the size in the group of 12 animals receiving the mutated prolactin.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Sept 12, 2000

Ameae M. Walker

Atty. Docket: 2500.097US2

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